

K122359



AUG 28 2012

## 510(k) SUMMARY

### VITEK® 2 *Streptococcus* Ceftriaxone

#### 510(k) Submission Information:

Submitter's Name: bioMérieux, Inc.  
Address: 595 Anglum Road  
Hazelwood, MO 63042  
Contact Person: Thi My Lan Dang  
Regulatory Affairs Officer  
Phone Number: 314-731-8799  
Fax Number: 314-731-8689  
Date of Preparation: June 12<sup>th</sup>, 2012

#### B. Device Name:

Formal/Trade Name: VITEK® 2 *Streptococcus* Ceftriaxone  
Classification Name: 21 CFR 866.1645  
Antimicrobial Susceptibility Test  
Product Code LON  
Common Name: VITEK® 2 AST-ST Ceftriaxone (CRO)

C. Predicate Device: VITEK® 2 AST-GP Amoxicillin for *S. pneumoniae* (K063597)

#### D. 510(k) Summary:

VITEK® 2 *Streptococcus* Ceftriaxone is designed for antimicrobial susceptibility testing of *Streptococcus* species. VITEK® 2 *Streptococcus* Ceftriaxone is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.

Ceftriaxone has been shown to be active against most strains of the following microorganism, according to the FDA label for this antimicrobial.

#### Active *In Vitro* and in Clinical Infections against:

*Streptococcus pneumoniae*  
*Streptococcus pyogenes*  
*Streptococcus agalactiae*  
viridans group streptococci

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK® 2 Compact Systems for the automated quantitative or qualitative susceptibility testing of

#### bioMérieux, Inc.

595 Anglum Road, Hazelwood, Missouri 63042-2320, USA Phone: 314/731-8500 800/638-4835 Fax: 314/731-8700  
<http://www.biomerieux-usa.com> Page 239

isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus spp.* and clinically significant yeast.

The antimicrobial presented in VITEK® 2 AST cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/mL. The VITEK® 2 AST cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The isolate to be tested is diluted to a standardized concentration with 0.45% to 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK® 2 automatically fills, seals and places the card into the incubator/reader. The VITEK® 2 Compact has a manual filling, sealing and loading operation. The VITEK® 2 Systems monitor the growth of each well in the card over a defined period of time (up to 36 hours for yeast). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK® 2 *Streptococcus* Ceftriaxone demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA. Issued August 28, 2009.

The Premarket Notification (510[k]) presents data in support of VITEK® 2 *Streptococcus* Ceftriaxone. An external evaluation was conducted with fresh and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to confirm the acceptability of VITEK® 2 *Streptococcus* Ceftriaxone by comparing its performance with the CLSI broth microdilution reference method. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms. VITEK® 2 *Streptococcus* Ceftriaxone demonstrated acceptable performance of 98.9% overall essential agreement and 97.2% overall category agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results using both the VITEK® 2 and VITEK® 2 Compact instrument systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue  
Silver Spring, MD 20993

bioMerieux, Inc.  
c/o Thi My Lan Dang  
Regulatory Affairs Officer  
595 Anglum Road  
Hazelwood, Missouri 63042

AUG 28 2012

Re: k122359  
Trade Name: VITEK® 2 AST Streptococcus Ceftriaxone  
Regulation Number: 21 CFR §866.1645  
Regulation Name: Fully automated short-term incubation cycle antimicrobial  
susceptibility system  
Regulatory Class: Class II  
Product Codes: LON  
Dated: August 1, 2012  
Received: August 3, 2012

Dear Ms. Dang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

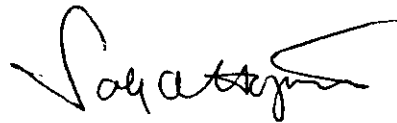
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sally A. Hojvat", with a stylized flourish at the end.

Sally A. Hojvat, M.Sc., Ph.D  
Director  
Division of Microbiology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K122359

Device Name: VITEK® 2 *Streptococcus* Ceftriaxone  
( $\leq 0.125 - \geq 8$  µg/mL)

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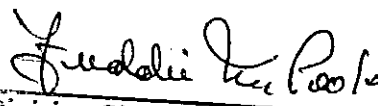
The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 System for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus spp.* and clinically significant yeast.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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